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Attorney Docket No. S63.2B-13170-US01

**Remarks**

This Amendment is in response to the Office Action dated November 2, 2006.

**Rejections**

**35 U.S.C. §102(b)**

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**Claims 1, 2, 4-8, 10, 11, 13-16, 18, 20, and 21**

The 35 U.S.C. § 102(b) rejection of claims 1,2, 4-8, 10, 11, 13-16, 18, 20, and 21 made of record in Office Action mailed on July 18, 2006 has been repeated for the reasons previously made of record and for the following reasons that address the amendments in claims 1, 10, 18.

The Office Action asserts that:

In regard to claims 1, 10, 18 Vigil et al. disclose an elongated, inflatable balloon (12, fig. 1) having an outer surface (18, fig. 1), at least one incising component (28a, fig. 1) positioned on said surface of balloon, a pad (32, adjacent to incisor, fig. 3A) having a outer surface, wherein said pad is positioned on said balloon, spaced apart from, substantially parallel to and juxtaposed with said incising component (incisor 31 of 28a is spaced apart from pad 32 of 28b, fig. 3A), said pad being located to engage said incising component with said outer surface of said pad to prevent damage to said balloon by said incising component when said balloon is in a deflated configuration (the atherotomes 28a,b,c are inherently capable of engaging each other because the balloon can be pressurized to deflate in a manner so that incisor 31 of atherotome 28a engages pad 32 of atherotome 28b).

Applicants disagree.

Fig. 3B of Vigil 35 al. illustrates the balloon 12 in a deflated state. As can be clearly seen from this figure, incisor 31 of atherotome 28a does not engage pad 32 of atherotome 28b when the balloon 12 is deflated. Applicants submit that it is improper to suggest from the

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disclosure of Vigil et al. that the balloon can be deflated in a manner different than that disclosed in the reference and in doing so, basing a rejection on a feature that the reference simply fails to disclose.

Applicants' pad, as can be clearly seen from the figures, particularly Fig. 3C of the present application, for example, is positioned adjacent to the incising component in such a manner that when the balloon is deflated as shown similarly in Fig. 3B of Vigil et al., the pad engages the incising component.

FIG. 3B of the present application (below left) is illustrative of a balloon 14 prior to deflation and shows the position of the incising component 20a with respect to pad 22a. FIG. 3A of Vigil et al. (below right) represents balloon 12 prior to deflation and shows the position of incisor 31 of atherotome 28a with respect to substrate 32 are reproduced below:

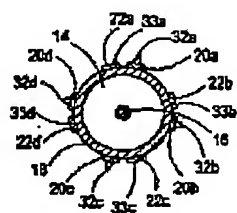


Fig. 3B

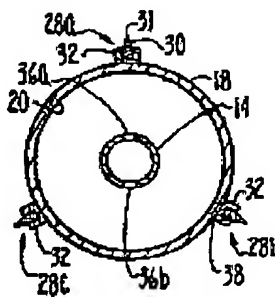


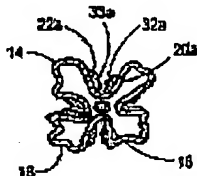
Fig. 3A

Applicants submit that the positioning of the pad 32 with respect to the incisor 28a as shown in FIG. 3A of Vigil et al. precludes engagement of pad 32 with incisor 28a upon deflation of the balloon as suggested in the Office Action.

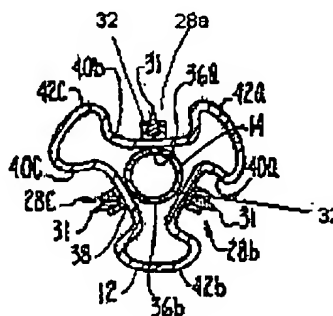
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The following Fig. 3B of Vigil et al. (below right) and Fig. 3C of the present application (below left) represent the balloons of FIG. 3A and 3B in a deflated state:



**Fig. 3C**



**Fig. 3B**

As shown in Fig. 3C of the present application (left), outer surface 33a of pad 22a engages cutting surface 32a. See page 8 of the present application for the description of Fig. 3C. In contrast, as shown in Fig. 3B of Vigil et al. (right), incisor 31 of atherotome 28(a) fails to engage pad 32 of adjacent atherotome 28b. The inventions are not the same as required by 35 U.S.C. §102(b).

Applicants have amended the independent claims 1, 10 and 18 of the present application so that each claim more clearly recites that the pad engages the incising component when the balloon is in a deflated configuration. No new matter has been added.

Claims 1, 10 and 18 are therefore not anticipated by Vigil et al. Claims 2 and 4-8 depend from claim 1 and are not anticipated by Vigil et al. for at least the reasons that claim 1 is not anticipated by Vigil et al. Claims 11, and 13-16 depend from claim 10 and are not anticipated by Vigil et al. for at least the reasons that claim 10 is not anticipated by Vigil et al. Claims 20 and 21 depend from claim 18 and are not anticipated by Vigil et al. for at least the reasons that claim 18 is not anticipated by Vigil et al.

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Based on the foregoing, Applicants respectfully request withdrawal of the rejection of claims 1, 2, 4-8, 10, 11, 13-16, 18, 20 and 21 under 35 U.S.C. §102(b) as anticipated by Vigil et al., U.S. Patent No. 5,320,634.

**Claims 1, 3, 4, 6-8, 12 and 19**

Claims 1, 3, 4, 6-8, 12, 19 have been rejected under 35 U.S.C. §102(e) as anticipated by O'Brien (U.S. 2005/0015107) for the reasons previously made of record.

The examiner upholds the rejection that the pad is formed on the outer surface of said balloon as a homogeneous structure with said balloon (para. 0028, with reference to figs. 6 and 7). The applicants' response on page 9, paragraph 4 of the response to amendment refers to another embodiment of the invention of O'Brien. As stated in the prior Office action, the Examiner refers to figures 6 and 7 (para. 0028) of O'Brien, not figures 9 and 10, which illustrates the embodiment of a "jacket".

Applicants disagree.

Applicants submit that Figs. 6 and 7 of O'Brien illustrate a catheter 112 for anchoring a balloon 114 at a treatment site:

In this embodiment, the catheter 112 includes three protuberances 136a-c that are formed as raised ridges with each ridge extending radially from the wall 132 of the flexible member 124 to a relatively sharp edge 56 that is aligned substantially parallel to the longitudinal axis 134. At a treatment site, the balloon 114 can be inflated to embed the protuberances 136a-c into a lesion or vessel wall to anchor the balloon 114 at the treatment site. *With cross-reference to FIGS. 6 and 7, it can be seen that the wall 132 and protuberances 136 are formed together in a unitary, one-piece construction, and accordingly, are both made of the same material which is typically polyethylene terephthalate (PET).* With this cooperation of structure, the wall 132 seamlessly interconnects the protuberances 136 together.

Paragraph [0028] (emphasis added).

Applicants submit that independent claims 1, 10 and 18, have been amended, and now all recite that the pad and incising component (claims 1 and 18) and the protective means

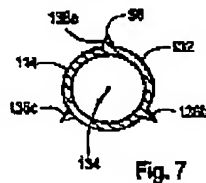
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and the incising means (claim 10) are "separated from" one another. Although Applicants still maintain that the previously employed term "spaced apart from" is sufficient to distinguish the claims of the present application over O'Brien, "separated from" should even further clarify the position of the pad or protective means with respect to the incising component of the present claims.

Therefore, O'Brien, which discloses protuberances 136a-c and wall 132 which are part of a unitary one-piece construction (flexible member 124; Figs. 6 and 7) does not anticipate claims 1, 10 and 18 of the present application because the pad or protective means and the incising component recited therein are "separated from" one another.

Applicants have reproduced Fig. 6 of O'Brien below which clearly illustrates that wall 132 and protuberances 136a-c do indeed form a unitary one-piece construction:



Claims 1, 10 and 18 are not anticipated by O'Brien. Claims 3, 5 and 6-8 depend from claim 1 and are not anticipated by O'Brien for at least the reasons that claim 1 is not anticipated by O'Brien. Claim 12 depends from claim 10 and is not anticipated by O'Brien for at least the reasons that claim 10 is not anticipated by O'Brien. Claim 19 depends from claim 18 and is not anticipated by O'Brien for at least the reasons that claim 18 is not anticipated by O'Brien.

Applicants respectfully request withdrawal of the rejection of claims 1, 3, 4, 6-8,

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12<sup>1</sup> and 19 under 35 U.S.C. §102(e) as anticipated by O'Brien (U.S. 2005/0015107).

**Claims 9, 17 and 22**

Claims 9, 17, 22 are rejected under 35 U.S.C. §103(a) as being unpatentable over Vigil et al. in view of Grayzel et al. (U.S. 6942680) for the reasons previously made of record.

The Office Action asserts that:

....it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the base as disclosed by Vigil et al. to include stiffeners as taught by Grayzel in order to gain the advantage of increasing the stiffness of the balloon. Such a modification would provide a stiffened base which in turn would help stiffen the balloon and prevent "kinks" in the balloon.

Applicants traverse the rejection.

Applicants submit that a *prima facie* case of obviousness under 35 U.S.C. §103(a) has not been made. Obviousness under 35 U.S.C. §103(a)

Where claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. See *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure.

*In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991). See also MPEP §2142.

Applicants submit that even if there was some motivation to combine Grayzel with Vigil et al. without using any hindsight, a *prima facie* case of obviousness has not been met because the combination of Vigil et al. and Grayzel fail to suggest a balloon wherein the pad and incising component are separated from one another prior to deflation of the balloon, and wherein

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the pad engages the incising component when the balloon is in a deflated configuration as recited in independent claims 1, 10 and 18.

The flexible member 124 as shown in Figs. 6 and 7 of Vigil et al. is a unitary one-piece construction which includes protuberances 136a-c and wall 132, wherein in contrast, the pad or protective means and incising component recited in claims 1, 10 and 18 are "separated from" one another. Combining the stiffeners of Grayzel as suggested in the Office Action, with the flexible member 124 of Vigil et al. fails to render claims 1, 10 and 18 obvious over this combination.

Claims 9, 17 and 22 depend from claims 1, 10 and 18 respectively and are patentable over Vigil et al. in view of Grayzel for at least the reasons that claims 1, 10 and 18 are patentable over Vigil et al. in view of Grayzel.

Applicants respectfully request withdrawal of the rejection of claims 9, 17 and 22 under 35 U.S.C. §103(a) as being unpatentable over Vigil et al. in view of Grayzel et al. (U.S. 6942680).

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**CONCLUSION**

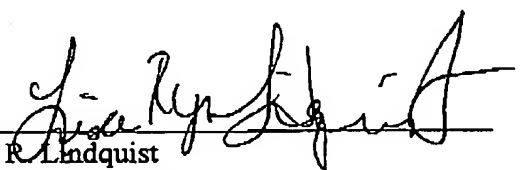
**DEC 22 2006**

Claims 1-22 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: December 22, 2006

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